PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

TAKEHISA, Toru et al. Group Art Unit: 3762

Application No.: 09/964,894 Examiner: Joseph S. Machuga

Filed: September 28, 2001

For: ARTIFICIAL LUNG OF MEMBRANCE TYPE

DECLARATION UNDER 37 CFR §1.132

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

I, Toshiaki Matsuda, do hereby declare and state that:

I graduated from Kogakuin University, Faculty of Engineering, Department of Industrial Chemistry in March of 1990 and, in March of ~~1970~~ 1992, received a Master's degree in the Graduate School of Industrial Chemistry, Kogakuin University. T.M. 4/18/05

In April of 1992, I was employed by Dainippon Ink and Chemicals, Inc. and since that time I have been principally engaged in research and development relating to medical devices.

The following comparative experimentation was conducted by me or under my supervision to demonstrate the unexpected superiority of the presently claimed invention.

EXPERIMENTATION

Production Example X:

Poly-4-methylpentene-1 having a melt index (determined according to ASTM D1238) of 26 was melt-spun by using a torus nozzle (diameter: 6 mm) for hollow fiber at a spinning temperature of 290°C, at a taking-off speed of 100 m/min, and at a draft (the winding/extrusion speed ratio) of 270 to thereby give hollow fiber of 275 μm in outer diameter and 34 μm in membrane thickness. In this step, the hollow fiber located from 3 to 35 cm under the nozzle port was cooled with an air stream at a temperature of 25°C at a flow rate of 1.5 m/sec. The hollow fiber thus obtained was continuously drawn in the amorphous state at a temperature of 35°C at a draw ratio (DR) of 1.05 with the use of a roller system. Subsequently, it was heat-treated by introducing into a hot air-circulation type thermostat at 200°C at a DR of 1.4 and pooling therein for 5 seconds. Next, it was subjected to cold drawing (35°C, DR 1.2), hot drawing (150°C, DR 1.2) and heat fixation (200°C, DR 0.9)

to thereby give a hollow fiber membrane of 255 μm in outer diameter and 27 μm in membrane thickness.

Then, an artificial lung of membrane type (hereinafter referred to as the artificial lung X_0) having a membrane area of 0.8 m^2 was constructed by using this hollow fiber membrane. The gas permeation rate of the hollow fiber part of this artificial lung of membrane type X_0 determined in accordance with the pressure method as defined in ASTM D1434 was as follows: $Q(O_2) = 5.0 \times 10^{-4}$ $cm^3(STP)/(cm^2 \cdot sec \cdot cmHg)$.

Using the artificial lung X_0 obtained above and the solution (I) obtained in Synthesis Example 1 of the specification, an artificial lung (X1) having a coating film of the above-described solution (I) on the blood-contact face of the above-described artificial lung X_0 was constructed in the same manner as in Example 1 of the specification.

The artificial lung (X1) thus obtained was examined for its capability of eliminating carbon dioxide at various blood flow rates in accordance with the method as defined in ISO 7199. The results obtained are shown in Fig. A.

Production Example Y:

Poly-4-methylpentene-1 having a melt index (determined according to ASTM D1238) of 26 was melt-spun by using a torus nozzle (diameter: 6 mm) for hollow fiber at a spinning temperature of 290°C, at a taking-off speed of 100 m/min, and at a draft (the winding/extrusion speed ratio) of 270 to thereby give hollow fiber of 275 μm in outer diameter and 34 μm in membrane thickness. In this step, the hollow fiber located from 3 to 35 cm under the nozzle port was cooled with an air stream at a temperature of 25°C at a flow rate of 1.5 m/sec. The hollow fiber thus obtained was heat-treated by introducing into a hot air-circulation type thermostat at 200°C at a DR of 1.1 and pooling therein for 5 seconds. Next, it was subjected to cold drawing (35°C, DR 1.235), hot drawing (150°C, DR 1.4) and heat fixation (200°C, DR 0.9) to thereby give a hollow fiber membrane of 255 μm in outer diameter and 27 μm in membrane thickness.

Then, an artificial lung of membrane type (hereinafter referred to as the artificial lung Y_0) having a membrane area of 0.8 m^2 was constructed by using this hollow fiber membrane. The gas permeation rate of the hollow fiber part of this artificial lung of membrane type Y_0 determined in accordance with the pressure method as

defined in ASTM D1434 was as follows: $Q(O_2) = 1.2 \times 10^{-3}$ $cm^3(STP)/(cm^2 \cdot sec \cdot cmHg)$.

Using the artificial lung Y_0 obtained above and the solution (I) obtained in Synthesis Example 1 of the specification, an artificial lung (Y1) having a coating film of the above-described solution (I) on the blood-contact face of the above-described artificial lung Y_0 was constructed in the same manner as in Example 1 of the specification.

The artificial lung (Y1) thus obtained was examined for its capability of eliminating carbon dioxide at various blood flow rates in accordance with the method as defined in ISO 7199. The results obtained are shown in Fig. A.

Production Example Z:

Poly-4-methylpentene-1 having a melt index (determined according to ASTM D1238) of 26 was melt-spun by using a torus nozzle (diameter: 6 mm) for hollow fiber at a spinning temperature of 290°C, at a taking-off speed of 100 m/min, and at a draft (the winding/extrusion speed ratio) of 270 to thereby give hollow fiber of 275 μm in outer diameter and 34 μm in membrane thickness. In this step, the hollow fiber located from 3 to 35 cm under the nozzle port was cooled with an air stream at a temperature of 25°C

at a flow rate of 1.5 m/sec. The hollow fiber thus obtained was continuously drawn in the amorphous state at a temperature of 35°C at a draw ratio (DR) of 1.05 with the use of a roller system. Subsequently, it was heat-treated by introducing into a hot air-circulation type thermostat at 200°C at a DR of 1.5 and pooling therein for 5 seconds. Next, it was subjected to cold drawing (35°C, DR 1.2), hot drawing (150°C, DR 1.2) and heat fixation (200°C, DR 0.9) to thereby give a hollow fiber membrane of 255 μm in outer diameter and 27 μm in membrane thickness.

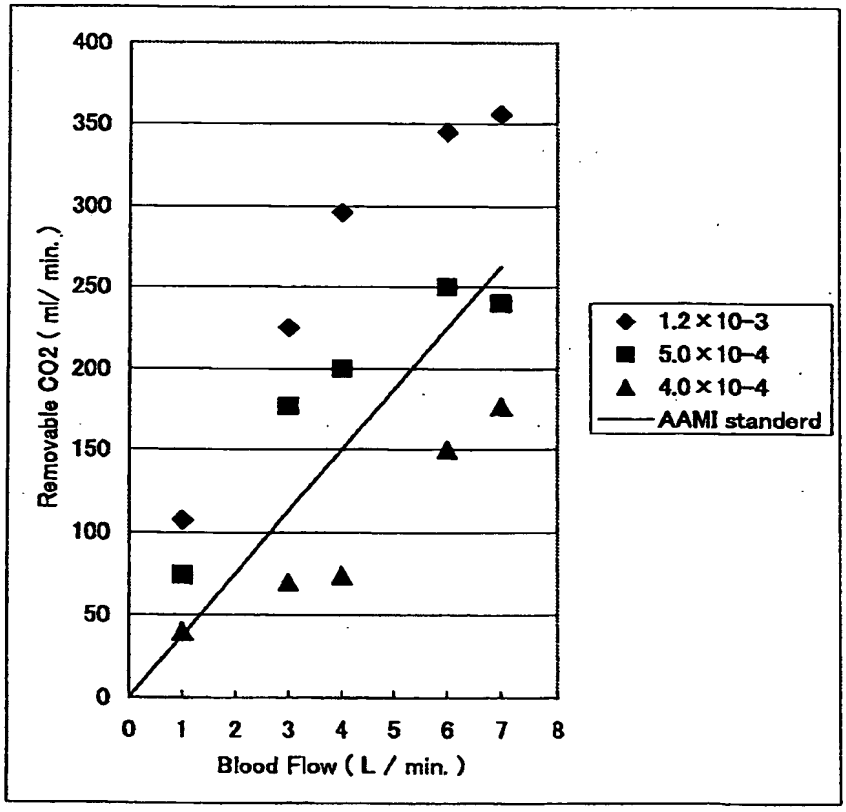
Then, an artificial lung of membrane type (hereinafter referred to as the artificial lung Z_0) having a membrane area of 0.8 m^2 was constructed by using this hollow fiber membrane. The gas permeation rate of the hollow fiber part of this artificial lung of membrane type Z_0 determined in accordance with the pressure method as defined in ASTM D1434 was as follows: $Q(O_2) = 4.0 \times 10^{-4}$ $cm^3(STP)/(cm^2 \cdot sec \cdot cmHg)$.

Using the artificial lung Z_0 obtained above and the solution (I) obtained in Synthesis Example 1 of the specification, an artificial lung (Z1) having a coating film of the above-described solution (I) on the blood-contact face of the above-described artificial lung Z_0 was

constructed in the same manner as in Example 1 of the specification.

The artificial lung (Z1) thus obtained was examined for its capability of eliminating carbon dioxide at various blood flow rates in accordance with the method as defined in ISO 7199. The results obtained are shown in Fig. A.

Fig. A



In Fig. A, the results of the carbon dioxide-eliminating capability of the artificial lungs (X1), (Y1) and (Z1) are indicated with the marks ■, ◆ and ▲, respectively. The oblique straight line in Fig. A indicates the AAMI standard for blood-gas exchange devices (The term "AAMI" means the Association for the Advancement of medical Instrumentation).

It can be seen from Fig. A that the artificial lung (Z1) using a hollow fiber membrane having an oxygen permeation rate lower than 5×10^{-4} (cm^3(STP)/(cm^2·sec·cmHg)) had an insufficient CO_2-removing amount and thus was not in the level of practically usable for clinical purpose. On the other hand, the artificial lungs (X1) and (Y1) using a hollow fiber membrane having an oxygen permeation rate within the claimed range substantially satisfied the AAMI standard and were capable of satisfactorily removing CO_2 in blood.

I declare further that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are

punishable by fine or imprisonment, or both, under 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Date: April 18, 2005 Toshiaki Matsuda

Toshiaki Matsuda